DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 29, 2003, from 8 a.m. to 5 p.m. and on May 30, 2003, from 8 a.m. to 12 noon.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, petersonj@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting. When available, background materials for this meeting will be posted 1 business day prior to the meeting on the FDA Web site at: www.fda.gov/ohrms/

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dockets/ac/acmenu.htm. (Click on the year 2003 and scroll down to Cardiovascular and Renal Drugs Advisory Committee meetings.)

Agenda: On May 29, 2003, the committee will discuss QT prolongation issues associated with two new drug applications (NDAs): (1) NDA 21–287, (alfuzosin HCl), Sanofi-Synthelabo Inc., for the proposed indication of treatment of the signs and symptoms of benign prostatic hyperplasia; and (2) NDA 21–400, Levitra (vardenafil HCl), Bayer Corp., proposed for the indication of treatment of erectile dysfunction. The discussion will focus on: (1) Clinical trial designs for assessment of QT prolongation; (2) approaches to the correction of QT interval for drugs that affect the heart rate; and (3) risks of cardiac arrythmias associated with different degrees of QT prolongation. Premarketing clinical safety data from these applications and postmarketing safety data relevant to cardiac QT prolongation from drugs in the same two drug classes (i.e., alpha adrenergic blockers and phosphodiesterase type 5 inhibitors) will be considered.

On May 30, 2003, the meeting will be closed to permit discussion and review of trade secret and/or confidential information.

Procedure: On May 29, 2003, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 21, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 29, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 21, 2003, and submit a brief statement of the general nature of the evidence or arguments

they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Presentation of Data: On May 30, 2003, the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jayne Peterson at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 4/24/03

April 24, 2003.

Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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